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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/897,455	07/22/1997	ULRICH STACHE	2481.1403-02	4518

7590

02/04/2002

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

08/897,455

Applicant(s)

STACHE ET AL.

Examiner

Barbara P Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☐ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 11-22 are pending in the present application. Claims 18-22 stand withdrawn from further consideration as being drawn to a non-elected invention. Claims 11-17 stand rejected as indicated below.

Claim Rejections - 35 USC § 103

3. **The rejection of claims 11-17 under 35 USC 103(a) over Page et al. ('971) is maintained.**

Applicant argues (a) there is no motivation to make selections of substituents from Page to approximate the claimed invention; (b) all of the exemplified compounds recite aliphatic group substituents in the 21-position; (c) the ordinary artisan would have been dissuaded from using the compounds of examples 9 and 19 as starting points for deriving new compounds and (d) the claimed compounds have been shown to possess unexpected superior properties. Applicant's arguments were considered but not persuasive for the following reasons.

As stated in previous Office Actions, the reference teaches specific compounds that differ from the claimed compounds by only one substituent (i.e., the substituent in

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the 21-position). The difference between the two substituents attached to the 21-position is in the kind of acyl group and, thus, the reference provides guidance to the ordinary artisan to select an acyl group in that position. Page teaches R of the acyl group can be one of three groups (i.e., an alkyl, an aralkyl or a phenyl). Replacing the acyl group of compounds exemplified by Page by one of the other two R group taught by the reference would be readily visualized by the skilled artisan. Therefore, the examiner does not agree that the issue here is analogous to that decided in In re Baird or that the ordinary artisan would not be motivated to make selections of substituents from the prior art to approximate the claimed invention.

Applicant's argument against examples 9 and 19 are again noted. The issue is whether the claimed compounds are made obvious in view of the teachings of the prior art and, not whether the ordinary artisan can use the compounds of examples 9 and 19 as starting compounds in making the claimed compounds. It is noted that the ordinary artisan does not have the use these compound as starting compounds as argued by applicant. Also as indicated in the previous Office Action, there are other examples taught by the reference that also differ from the claimed compounds only by the acyl group attached to the 21-position.

The comparative test shown in the present application is not persuasive because it is not a true side-by-side comparison of the closest prior art compound and the claimed compound. Any of the exemplified compounds disclosed by Page having an acyl group attached to the 21-position and differs from the corresponding claimed compound only by the absence of a phenyl substituted on the alkyl group of the acyl

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substituent would be considered a close prior art compound, for example, the compounds of examples 3-5 and 9. The comparison made in the present specification is between compounds that differ by more than one substituent.

For these reasons and those given in previous Office Actions, the rejection of claims 11-17 under 35 USC 103(a) over Page et al. ('971) is maintained.

4. The rejections of (a) claims 11, 12 and 14-17 over Djerassi et al. ('429); (b) claims 11, 12 and 15-17 over Bowers ('391) and (c) claims 11, 12, 13 and 15 over Oughton et al. ('940) under 35 USC 103(a) are maintained.

Applicant argues that the cited references do not motivate one skilled in the art to use an aralkyl substituted acyl group in the 21-position or to select said group from the groups specifically taught by the prior art. Applicant lists a number of patents and argues that the prior art as a whole would not have motivated one skilled in the art to make the claimed compound. Lastly, applicant argues the superior and surprising properties of the claimed compounds. Applicant's arguments were considered but not persuasive for the following reasons.

Each of the three references teaches a limited group of specific acyl groups that can be attached to the 21-position of the steroid moiety. Because of the limited number of substituents taught by the cited references (i.e., 13 in Djerassi; 11 in Bowers and 4 in Oughton), substitution in the 21-position of the steroid moiety by each one of these groups would be obvious to the skilled artisan.

The various other patents cited by applicant are noted. However, the issue is not how many patents or publication there are with similar compounds but whether the prior art makes obvious applicant's claimed compounds. The examiner maintains the position that the prior art makes obvious the claimed invention.

Lastly, applicant argues superior and surprising properties. The examiner's response is as indicated above in #3.

For these reasons and those given in Paper No. 35, the rejections of (a) claims 11, 12 and 14-17 over Djerassi et al. ('429); (b) claims 11, 12 and 15-17 over Bowers ('391) and (c) claims 11, 12, 13 and 15 over Oughton et al. ('940) under 35 USC 103(a) are maintained.

Other Matters

5. The examiner notes that the PTO 1449 indicated by applicant is not of record in the present application.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
January 31, 2002